

**SPECIFICATIONS FOR
THE QUALITY CONTROL
OF PHARMACEUTICAL
PREPARATIONS**

WORLD HEALTH ORGANIZATION

Specifications For The Quality Control Of Pharmaceutical Preparations

World Health Organization



Specifications For The Quality Control Of Pharmaceutical Preparations:

Specifications for the Quality Control of Pharmaceutical Preparations, 1967 **Specifications for the Quality Control of Pharmaceutical Preparations** World Health Organization, 1967 *Specifications for the Quality Control of Pharmaceutical Preparations* World Health Organization, 1971 *Specifications for the Quality Control of Pharmaceutical Preparations*, 1971 **WHO Expert Committee on Specifications for Pharmaceutical Preparations** World Health Organization, 2022-12-22

The WHO Technical Report Series 1044 presents the fifty sixth report by the WHO Expert Committee on the Specifications for Pharmaceutical Preparations It provides comprehensive standards and guidelines for the quality assurance of medicines developed through extensive international consultation The report includes new guidance on various aspects such as good manufacturing practices for sterile products technology transfer for medicinal gases and the stability studies of medical products The WHO s publications aim to support national health strategies and address pressing public health concerns by disseminating authoritative information and guidance globally This report reflects the collective views of international experts contributing to the WHO s mission to attain the highest possible level of health for all people

WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations, World Health Organization, 2014 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines Standards are developed by the Committee through worldwide consultation and an international consensus building process The following new guidelines were adopted and recommended for use in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances The International Pharmacopoeia updating mechanism for the section on radiopharmaceuticals WHO good manufacturing practices for pharmaceutical products main principles Model quality assurance system for procurement agencies Assessment tool based on the model quality assurance system for procurement agencies aide memoire for inspection Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities and Guidelines on submission of documentation for a multisource generic finished pharmaceutical product quality part

Specifications for the Quality Control of Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations, 1967 **The Quality Control of Medicines** P.B. Deasy, R.F. Timoney, 2014-05-21 The Quality Control of Medicines documents the proceedings of the 35th International Congress of Pharmaceutical Sciences organized by the Pharmaceutical Society of Ireland on behalf of the Federation Internationale Pharmaceutique held in Dublin on 15 September 1975 The theme chosen for the Congress was the basis for the quality control of medicines because of the importance and relevance of quality control in the production and distribution of medicines at national and international levels This volume is arranged according to the manner in which the theme of the Congress was developed by the eminent

invited speakers Following the inaugural address a main symposium was held where five speakers presented a review of the quality control of medicines under the general headings of i chemical and physical aspects ii biological aspects iii control of drug delivery systems iv storage problems and v problems of international control Certain aspects of the content of the main symposium were then developed in greater depth in parallel symposia In the first parallel symposium some novel physicochemical aspects of the quality control of medicines were treated under the headings of spectrofluorimetry mass spectrometry detection in gas chromatography and automation in pharmaceutical analysis The second parallel symposium developed certain microbiological aspects of quality control under the headings of sterility testing and microbiological control of non sterile products and ophthalmic preparations The final symposium on submissions to regulatory bodies and international aspects of drug control covered aspects of politics in submissions regulatory problems in small countries and various pharmacopoeial problems

WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting, World Health Organization, 2016 The World Health Organization WHO Expert Committee on Specifications for Pharmaceutical Preparations advises the Director General of WHO in the area of medicines quality assurance It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States Its advice is developed through a broad consensus building process and covers all areas of quality assurance of medicines from their development to their distribution to patients In the area of quality control the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines HealthCare EDQM the custodian centre for International Chemical Reference Substances ICRS The Committee adopted a number of monographs general texts and ICRS It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme EQAAS and on new approaches to ensure sustainability of this scheme through user fees The Committee further acknowledged the progress of good pharmacopoeial practices GPhP and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias In the various quality assurance related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices GMP distribution and trade of pharmaceuticals and regulatory practice It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project

WHO Expert Committee on Specifications for Pharmaceutical Preparations WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting, 2015-05-11 The World Health Organization WHO Expert Committee on Specifications for Pharmaceutical Preparations advises the Director General of WHO in the area of medicines

quality assurance It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States Its advice is developed through a broad consensus building process and covers all areas of quality assurance of medicines from their development to their distribution to patients In the area of quality control the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines Annex 2 Updating mechanism for the section on radiopharmaceuticals in The International Pharmacopoeia revision Annex 3 Supplementary guidelines on good manufacturing practices validation Appendix 7 non sterile process validation revision Annex 4 General guidance for inspectors on hold time studies new Annex 6 Recommendations for quality requirements when plant derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients revision Annex 7 Guidelines on registration requirements to establish interchangeability revision Annex 8 Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource generic products revision Annex 9 Good review practices guidelines for regulatory authorities new In addition 16 technical supplements to the WHO model guidance for the storage and transport of time and temperature sensitive pharmaceutical products were adopted for publication in a format which is appropriate to the large volume of this guidance Annex 5 The newly adopted monographs were adopted for inclusion in The International Pharmacopoeia Following the implementation of the revised general monograph on parenteral preparations the Committee adopted the proposed endotoxin limits for 11 parenteral dosage form monographs lacking such specification together with related updates to relevant monographs The Committee adopted 12 ICRS newly characterized by the custodian centre EDQM The Committee further adopted the workplan for new monographs to be included in The International Pharmacopoeia

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